a-Asn-Lys-Gly-Glu-Asn-Thr-Ser-Leu-Leu-His-Pro-Val-Ser-Leu-His-Gly-Met-Asp-Asp-Pro-Glu-Arg-Glu-Val-Leu-Glu-Trp-Arg-Phe-Asp-Ser-Arg-Leu-Ala-Phe-His-His-Val-Ala-Arg-Glu-Leu-His-Pro-Glu-Tyr-Phe-Lys-Asn-Cys;

(c) the peptide having the following sequence of

ORF-1:

Met-Glu-Gln-Ala-Pro-Glu-Asp-Gln-Gly-Pro-Gln-Arg-Asp-Pro-His-Asn-Glu-Trp-Thr-Leu-Gln-Leu-Leu-Glu-Glu-Leu-Lys-Asn-Glu-Ala-Val-Arg-His-Phe-Pro-Arg-Ile-Trp-Leu-His-Gly-Leu-Gly-Gln-His-Ile-Tyr-Glu-Thr-Tyr-Gly-Asp-Thr-Trp-Ala-Gly-Val-Glu-Ala-Ile-Ile-Arg-Ile-Leu-Gln-Gln-Leu-Leu-Phe-Ile-His-Phe-Arg-Ile-Gly-Cys-Arg-His-Ser-Arg-Ile-Gly-Val-Thr-Gln-Gln-Arg-Arg-Ala-Arg-Asn-Gly-Ala-Ser-Arg-Ser; and

(d) the peptide having the following sequence of

ORF-4:

Met-Gln-Pro-Ile-Gln-Ile-Ala-Ile-Ala-Ala-Leu-Val-Val-Ala-Ile-Ile-Ile-Ala-Ile-Val-Val-Trp-Ser-Ile-Val-Ile-Ile-Glu-Tyr-Arg-Lys-Ile-Leu-Arg-Gln-Arg-Lys-Ile-Asp-Arg-Leu-Ile-Asp-Arg-Leu-Ile-Glu-Arg-Ala-Glu-Asp-Ser-Gly-Asn-Glu-Ser-Glu-Gly-Glu-Ile-Ser-Ala-Leu-Val-Glu-Met-Gly-Val-Glu-Met-Gly-His-His-Ala-Pro-Trp-Asp-Ile-Asp-Asp-Leu.--

3' Cont.

REMARKS

Applicants acknowledge with appreciation the courtesy extended by the Examiner to allow the telephonic interview of October 9, 1996. Applicants have incorporated the suggested claim language as per that interview in newly added claims 17-19.

Support for this amendment is found throughout the specification, for example, at pages 12-13, and at page 15, line 30, to page 16, line 9. Accordingly, this amendment does not raise new matter and entry is respectfully requested.

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The only remaining issue is the rejection of claims 11, 13, and 15 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kalayanarman or Schupbach et al. as evidenced by Arya et al., Wong-Staal, and Cohen et al.

The Examiner maintains that the claim terminology "purified" is broadly interpreted such that the cited references embody the claims. In particular, the Examiner states that the isolation of antisera from HIV-infected patients as allegedly taught by Kalayanarman and Schupbach et al. is within the scope of the claims. Applicants respectfully traverse the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Vedegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that neither Kalyanarman nor Schupbach et al. teach the claimed invention. Neither reference teaches the claimed antibody or immunological complex. However, the Examiner states that the claimed antibodies and immunological complexes are inherently present in antiserum of an HIV-1 infected patient. Applicants submit that the Examiner does not properly interpret the claims, which recite a "purified antibody" and a "purified immunological complex."

In order to properly interpret the meaning of words in a claim, the specification can provide relevant information about the scope and meaning of the claim. Loctite v. Ultraseal, 791 F.2d 861, 886, 228 U.S.P.Q. 90, 93 (Fed. Cir. 1985). The specification provides that antibodies and the conventional methods of producing and screening for them are within the scope of the invention. *See* specification, page 15, line 25, through page 16, line 5. Such conventional

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methods further relate to the purification of the claimed subject matter, which would seemingly require the screening for these products.

For example, Harlow et al. (Exhibit 1) describe sampling serum for the production of specific antibodies. At page 116 of the reference, the authors state "Comparing the titers of antibodies isolated after successive injections [of an antigen] allows the antibody response to be monitored." Harlow et al. further teaches that "Normally, small samples [of serum] are collected until the desired antibodies are detected and the levels have reached acceptable levels. . . . Test bleeds normally are assayed against the immunogen itself by one of the techniques described." (Harlow et al., page 116, second and third paragraph.) Thus, one having ordinary skill in the art would appreciate that the antibody and immunological complexes must be detectable in order to be within the scope of being "purified" as claimed herein. In fact, this is confirmed in Harlow et al. at page 290, wherein the authors discuss the importance of antigen binding activity in order to purify antibodies:

> **Antigen binding activity** Compare the purified antibody to the starting material in a series of titrations, normalizing to the total amount of antibody in each preparation. This should give a good estimate of the loss of activity through purification. (Emphasis in original.)

However, Kalyanaraman and Schupbach et al. do not teach screening for the antibodies and immunological complexes of the claimed invention.

Harlow et al. further describes the criticality of designing and choosing the appropriate peptide sequence for use as an immunogen. For example, it is noted that "[w]hen considering

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which sequence to use, most people actually want to know how likely will it be that the anti-peptide antibodies will recognize the native protein." (Harlow et al., page 75, second paragraph.) Thus, eliciting an antibody response to a particular antigen may be dependent upon the selection of the antigen.

Here, Applicants leave no question as to what immunogen is used to elicit an antibody response. Kalyaranam and Schupbach et al., on the other hand, make no mention or suggestion as of the peptides recited in the claims, which are capable of producing the claimed antibodies and immunological complexes. In order to show an inherently anticipatory disclosure, each and every element of claimed invention must "flow undeniably from the express disclosure" of either Kalyanaraman or Schupbach et al. *See* Hughes Aircraft Co. v. U.S., 8 U.S.P.Q.2d 1580, 1583 (Ct. Cl. 1988). However, none of these references teach the claimed purified antibodies and purified immunological complexes. The authors merely obtained serum samples from patients infected by HIV-1 and reported responses to antigens other than the peptides recited in the claims. No mention is made at all regarding the specific antigens to which Applicants' antibodies react.

In order to remedy this deficiency, the Examiner relies upon Arya, Wong-Staal, and Cohen to suggest that these antibodies are present in the sera. Again, reliance upon these references does not take into account Applicants' claims, which recite purified antibodies and immunological complexes. Thus, for the reasons set forth above, these evidentiary references are insufficient to support an anticipation rejection over the claimed invention.

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Applicants respectfully submit that the rejection is improper and withdrawal is respectfully requested.

Moreover, Applicants have added new claims 17-19, which recite monoclonal antibodies, which bind with the claim-designated peptides. In the event that the Examiner maintains the instant rejection over claims 11, 13, and 15, it is submitted that, at the very least, claims 17-19 are patentable over the prior art.

Entry of this Amendment, reconsideration of this application, and the issuance of a prompt notice of allowance is courteously requested. The Examiner is invited to call the undersigned to discuss the remaining issues in order to expedite prosecution.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 11, 13, 15, and 17-19 in condition for allowance. Applicants submit that the proposed amendments of the claims do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Moreover, Applicants submit that the entry of the Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under

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37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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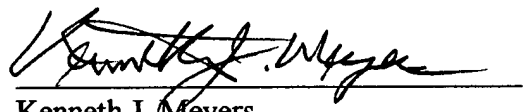
By: 
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